SNM/ACNP Government Relations Update

The following outlines some initiatives of the joint Government Relations Office of The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP), including some provisions of the 1990 Congressional Budget that affect nuclear medicine.

Department of Health and Human Services Reimbursement Issues:

■ Medicare Reimbursement

The Omnibus Budget Reconciliation Act (OBRA) of 1990 includes an amendment to extend the rule separating nuclear medicine from the radiology fee schedule. Reimbursement to nuclear medicine physicians will continue to be based on the 1990 blended rate of 1/3 of the Radiology Relative Value Scale (RVS) and 2/3 of 101% of the 1988 prevailing charge. This partial exemption applies to physicians for whom nuclear medicine services account for at least 80% of their Medicare Part B billing.

However, the legislation did not address nuclear medicine's transition into a Resource-Based Relative Value Scale (RBRVS) in 1992. The Health Care Financing Administration's (HCFA) legislative counsel advised Congressional conferees that it was unnecessary to insert such language. It was counsel's opinion that HCFA already has the authority to manipulate the fee schedules administratively.

In an effort to clarify this issue, ACNP President Robert E. Henkin, MD, and SNM RBRVS Task Force Chair Barbara Y. Croft, PhD, met with representatives of HCFA's Office of Payment Policy in December 1990. The group discussed the 1992 transition extensively, and HCFA indicated that it would publicly announce its decision in its April RBRVS report to Congress.

In the meantime, the SNM/ACNP Government Relations Office will be working with Congress to clarify the process of integrating nuclear medicine into the RBRVS through the 1991 Technical Amendments Act, which amends the 1990 OBRA legislation. The Technical Amendments are expected to come to the floor for consideration in the spring of 1991.

■ Model Fee Schedule

HCFA published "The Medicare Program; Model Fee Schedule for Physicians' Services" in the September 4, 1990 *Federal Register.* The fee schedule does not address nuclear medicine reimbursement specifically, because it assumed that these services would remain under the Radiology RVS. In a statement to the Department of Health and Human Services (HHS) Secretary, the SNM and the ACNP commented that nuclear medicine is a separate and distinct specialty and that the Harvard-developed values provide a more objective basis for reimbursement.

■ Harvard RBRVS

In Phase III of the Harvard RBRVS study, consensus panel members are to determine all values for nuclear medicine services based on the Harvard-developed example values. In response to a request from the Physician Payment Review Commission (PPRC) and the American Medical Association (AMA), the SNM and the ACNP have recommended 30 physicians for the expert panel on nuclear medicine. The panel is expected to begin work by June of 1991.

■ Testimony to Physician Payment Review Commission

On behalf of the SNM and the ACNP, Dr. Henkin presented testimony during a December 1990 PPRC hearing on the Commission's draft annual report to Congress (due March 1991). One of the topics to be included in the PPRC's 1991 report is "Integrating Radiology Services into the Medicare Fee Schedule." The PPRC appears sympathetic to the SNM and the ACNP's argument that after 1992 nuclear medicine reimbursement should be determined by the RBRVS rather than the radiology fee schedule. Dr. Henkin also recommended that ". . .the physician time and effort for compliance with instrumentation and radiopharmaceutical quality control and quality assurance protocols. . ." be considered as work values for nuclear medicine services. PPRC Director Paul B. Ginsberg, PhD, acknowledged this issue and assured Dr. Henkin that the Commission would be reviewing it for its final report.

■ SPECT Reimbursement

Despite HCFA's policy of reimbursing single-photon emission computed

tomography (SPECT) under Medicare, Medicare reimbursement for SPECT is often inadequate and inconsistent. HCFA has decided to initiate a rulemaking process to establish a national reimbursement policy for all SPECT services. The agency is expected to publish an announcement requesting comments on such a policy in the *Federal Register* before the summer of 1991.

■ Medicare "Hassle Factor"

Included in OBRA 1990 are several provisions from a Medicare "anti-hassle" bill sponsored by Representative Roy Rowland, MD (D-GA). To provide insight into how Medicare makes individual reimbursement decisions, HCFA will initiate test projects on the utility of releasing medical screens to physicians. In addition, the legislation allows physicians to provide coverage for one another by permitting the regular doctor to bill as if they had performed the service, provided the *locum tenens* arrangement is in place for 60 days or less.

■ Revisions to ICD-9-CM for Nuclear Medicine Services

The ICD-9-CM Coordination and Maintenance Committee plans to completely revise all codes for nuclear medicine services (92.xx series of ICD-9-CM). The Coordination and Maintenance Committee consists of representatives from the Public Health Service and the National Center for Health Statistics. Positron emission tomography (PET), total body scans, and monoclonal antibodies were specifically identified as procedures the panel would like modified in the coding system. The Committee sees revisions necessary due to: (1) inaccurate descriptions that do not adequately represent nuclear medicine procedures and (2) a lack of codes for new procedures. The Committee has encouraged the nuclear medicine community to suggest revisions to the codes for nuclear medicine services. A meeting for all interested parties had been arranged for January 16, 1991. Representatives from industry, the American Hospital Association (AHA), and the American College of Radiology (ACR) have expressed interest in participating in the revision process.

■ DPA/SPA Assessment

The Office of Health Technology Assessment (OHTA) is reviewing the responses to the April 1990 *Federal Register* notice announcing their reassessment of dual-photon absorptiometry and single-photon absorptiometry. It is unclear when a recommendation may be forthcoming. In a Congressional effort to provide Medicare reimbursement for the various bone mass measurement technologies, Senator John Glenn (D-OH) introduced a version of a bill in the Senate and Representative Olympia Snowe (R-ME) brought the measure to the House. Although the legislation was not passed, it is expected to be reintroduced next year.

■ PET Assessment and Reimbursement

OHTA's assessment of PET appears to be at a standstill. Rumor has it that the assessment has been completed. However, until the FDA approves fluorine-18 fluorodeoxyglucose (FDG), the document is on hold. The Institute for Clinical PET (ICP) has developed a Drug Master File to assist FDA in the review of FDG. The final word on approval is expected by early 1991.

Food and Drug Administration:

■ PET Pharmaceuticals

In a letter sent to former FDA Commissioner Benson, the SNM and the ACNP clearly outlined their position that the dispensing, compounding, and administering of PET pharmaceuticals by physicians is the practice of medicine and pharmacy. As FDA continues to move forward on the regulation of PET drugs, it was important to make a clear distinction between manufactured radiopharmaceuticals and those compounded by a physician. Although the September 21, 1990 letter requested a response, none has been received.

■ FDA Commissioner

David A. Kessler, MD, JD, assumed the post of FDA Commissioner on November 8, 1990. Most recently, Dr. Kessler served as medical director of the Hospital of the Albert Einstein College of Medicine, Bronx, New York.

■ HHS FDA Advisory Committee

Representatives of the SNM and the ACNP presented the concerns of nuclear medicine to the HHS Advisory Committee on the FDA, which is also known as the "Blue Ribbon Commission." Darrell W. McIndoe, MD, staff nuclear medicine physician at St. Joseph's Hospital, Towson, Maryland, presented testimony before the Subcommittee on Medical Devices, Radiological Products and Biomedical Research on October 15, 1990. Robert F. Carretta, MD, co-director of the department of nuclear medicine at Roseville Hospital in California, associate clinical professor at University of California (UC), San Francisco, assistant clinical professor at UC, Davis, spoke before the Subcommittee on Drugs and Biologics on November 8, 1990. The mission of the Advisory Committee is to evaluate the organization and functions of the FDA and to make recommendations to the HHS Secretary on how the organization and functions of the FDA can be improved. The panel includes members from the FDA, regulated industry, and medical and consumer organizations. The Advisory Committee has issued an interim report, which is available from the SNM/ACNP Washington Office. The Committee's final report is due by the end of May 1991.

■ FDA Reorganization

Since their first meeting with then FDA Commissioner Young in 1986, the SNM and the ACNP have been attempting to streamline the review process for radiopharmaceuticals, given their nearly nonexistent toxicity. Efforts to separate the review of radiopharmaceuticals into a unique division continue. There may be an opportunity for this as Commissioner Kessler reorganizes many FDA divisions over the next year.

■ Safe Medical Device Act of 1990

The Safe Medical Devices Act of 1990 was signed into law as an amendment to the Food, Drug and Cosmetic Act (FDCA). The newly enacted legislation authorizes the FDA to impose sizeable civil penalties on users and manufacturers who do not report device failures. Fines are not to exceed $15,000 for each violation and are capped at $1 million per proceeding. The law also revises section 510(k) of the FDCA, pertaining to the approval of medical devices. The previous 510(k) process allowed a device to receive an expedited review if it was similar to one already approved. The new system bases 510(k) on "substantial equivalence," which is far more stringent.

■ FDA User Fees

The House and Senate conferees rejected user fees as a source of revenue for the FDA. User fees are favored by the Bush Administration, however, and are expected to be in the FY 1992 presidential budget proposal.

Department of Energy:

■ National Biomedical Tracer Facility

The SNM and the ACNP filed a grant application with the Department of Energy's (DOE) Office of Health and Environmental Research to solicit financial support for a National Biomedical Tracer Facility (NBTF) study. DOE approved the grant for $83,752. A task force comprised of representatives from the DOE, industry, and the SNM and the ACNP have met several times to develop the parameters of the study. The task force will submit a final document to the DOE for review in March. DOE will combine the task force document with information developed by the agency's Division of Isotope Production in testimony to be given before the Congressional Energy and Water Appropriations Committees during the spring of 1991.

■ DOE Appropriations for FY 1991

Appropriations for the DOE's Biological and Environmental Research Programs are $396,394,000. It is estimated that approximately $40,000 of these funds will support nuclear medicine-related projects.

Nuclear Regulatory Commission:

■ Interim Final Rule on Petition for Rulemaking Change

On August 23, 1990, the Nuclear Regulatory Commission (NRC) responded to the SNM/ACNP Petition for Rulemaking Change with an Interim Final Rule (see *Newsline,* November 1990, p. 20A). The rule became effective immediately and is in effect through August 23, 1993. The Interim Final Rule is more restrictive than what was requested in the Petition. The Rule requires extensive record-keeping for nuclear pharmacies, hospitals, and physicians. Deviations from package inserts are permitted only if the nuclear pharmacy "has a written directive made by an authorized user physician that directs a specific departure for a particular patient, or patients, or for a radiopharmaceutical . . ." Deviations are not permitted for radiopharmaceuticals used in therapy; nuclear pharmacies are also not allowed to compound non-Investigational New Drug (IND) or non-New Drug Application (NDA) radiopharmaceuticals under the Interim Final Rule. The Society and the College have submitted a letter to the NRC requesting how the Interim Final Rule is to be interpreted by the NRC. Of particular concern is what enforcement actions would be taken against physicians who used a radiopharmaceutical outside the package insert without satisfying the NRC criteria. The NRC's response is pending. In the meantime, discussions with NRC staff seem to be leaning toward a mutually acceptable compromise.

■ Quality Assurance Meetings

The NRC has held meetings with various interest groups to debate the Commission's proposed Quality Assurance Regulations. ACR has had two meetings with NRC staff on the issue. ACR's position is practically identical to that of the SNM and the ACNP; they strongly oppose any federal interference with the practice of medicine. The NRC also met with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to compare the NRC's proposed rule with existing JCAHO requirements on quality assurance. When the SNM and the ACNP met with NRC staff in July, the organizations argued that medical quality assurance is under the purview of the JCAHO. The NRC also called a meeting with ten Agreement States to discuss their quality assurance programs. On January 14 and 15, 1991, the NRC's Advisory Committee on the Medical Uses of Isotopes was to debate the regulation in depth.

■ NCRP — Study of Misadministrations/QA Rule

The National Council on Radiation Protection and Measurements (NCRP) has agreed to carry out a study on NRC's proposed rule on quality assur-

ance, detailing the radiobiological significance of nuclear medicine misadministrations. The study will be undertaken in response to a resolution adopted last year by the SNM Board of Trustees and the ACNP Board of Regents. According to Mr. William Ney, executive director of the NCRP, the Board has targeted late February - early March as the completion date. The NRC has also encouraged the NCRP study.

■ NRC User Fees/Appropriations

Included in OBRA 1990 is a provision to fund the NRC completely from user fees. Since 1987, the NRC has been funded 33% from user fees and 67% from federal monies. The new law has been effective since October 1, 1990 — the beginning of the federal government's FY 1991 budget cycle. The NRC's current operating costs are supported by federal dollars until a rulemaking process can determine how user and annual fees will be applied. A proposed rule is expected by June 1991. Once final, the 100% user fee system will be retroactive to include the entire 1991 fiscal year. The United States Council on Energy Awareness (USCEA) expects the nuclear power industry to be subject to the bulk of fee increases, however, medical licensees are certain to feel the impact as well.

Department of Transportation:

■ The Hazardous Materials Transportation Act

The Hazardous Materials Transportation Act (HMTA) was passed by Congress on October 26, 1990 and subsequently signed into law (P. L. 101-615) by President Bush in early November. According to HMTA, radioactive materials are included in the definition of hazardous materials. Radiopharmaceutical transportation is not expected to be regulated under this legislation, though the cost to manufacturers is also likely to be felt by the medical community.

Environmental Protection Agency:

■ The Clean Air Act

Nuclear medicine research and treatment was granted a two-year exemption from Clean Air Act regulations. In the original bill, all radionuclide emissions were subject to costly controls. Preliminary estimates indicate that compliance with the Act could have cost the medical community in excess of one million dollars annually. In the final hours of the 101st Congress, the Washington Office was able to insert an amendment that stayed the regulations for nuclear medicine. By 1993, the Environmental Protection Agency (EPA) Administrator is to determine if nuclear medicine is within an ample margin of safety under current NRC regulations.

■ The Resource Conservation and Recovery Act

The Resource Conservation and Recovery Act (RCRA) will be considered for reauthorization in 1991. This legislation will have a significant impact on the disposal of low-level radioactive waste and hospital mixed waste. Like the Clean Air Act, it intends to dual-regulate all radioactive wastes with the NRC.

Low-Level Radioactive Waste Lawsuits:

■ New York

The New York low-level waste litigation, *New York* v. *U.S.*, in which the State challenges the authority of the Federal Government to dispose of waste within the states, was settled on December 7, 1990 in favor of the defendants. Judge Cholakis of Albany Supreme Court dismissed the case on the grounds that a Congressional mandate to states regarding the disposal of low-level radioactive waste (LLRW) was constitutional. The SNM and the ACNP signed an *amicus curiae* (friend of the court) brief on behalf of the defendants. The State reportedly plans to appeal to the U.S. Supreme Court.

■ Nebraska

Although the State of Nebraska also lost a suit to prevent the siting of LLRW in that state, the new Governor, Ben Nelson, has pledged to oppose the site.

Allied Health Professions:

■ National Health Service Corps

The National Health Service Corps (NHSC) has been revitalized with appropriations of $91,735,000 for FY 1991. The NHSC gives priority to primary health services in health manpower shortage areas.

■ Free Trade Agreement

The United States-Canada Free Trade Agreement (FTA) was entered into on January 1, 1989. The FTA includes provisions to facilitate the temporary entry of professionals on a reciprocal basis. The SNM Technologist Section has requested that nuclear medicine and radiologic technologists be included among the professions recognized by the FTA.

■ Allied Health Grants and Contracts

The HHS appropriations plan also includes $1,659,000 for allied health grants and contracts, a significant increase over FY 1990 appropriations of $726,000.

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